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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/580,384

05/20/96

STEINEMANN

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D5715D

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EXAMINER

KISHORE, G

ART UNIT

PAPER NUMBER

1502

BENJAMIN ADLER  
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DATE MAILED:

01/13/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 - month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 22-25 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 22-25 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, <sup>Substantive</sup> PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, <sup>Substantive</sup> PTO-948

☐ Notice of Informal Patent Application, PTO-152

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. **Claims 22-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**‘Effective dose’ in claim 22 is indefinite; the function to be achieved should be recited after the said term.**

- It is unclear as to what applicants intend to convey by ‘activated protein C’ in claim 23. Does it mean that protein C is a zymogen and inactive?**

### ***Claim Rejections - 35 USC § 103***

2. **The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.**
3. **Claims 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galin or Iverson in combination with Bang and Esmon.**

**Galin teaches that the anticoagulant, heparin inhibits blood clotting and inflammation of eye (note the abstract, columns 2-3 and claims). Galin however, does not teach the use of Protein C.**

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**Iverson teaches that the intraocular fibrin formation during vitrectomy is inhibited by heparin (note the abstract and page 405). Iverson does not specifically teach the use of protein C.**

**Esmon teaches that Tumor necrosis factor (TNF) causes inflammatory changes at the endothelial cells and also stimulates microvascular thrombosis (note column 3, line 65 through col. 4, line 13). Esmon further teaches that activated protein C reduces the production of TNF (col. 4, line 41 et seq.).**

**Bang teaches that protein C enhances the lysis of fibrin. Bang further teaches that the activated protein C is a novel antithrombotic agent with wider therapeutic index than available anticoagulants such as heparin and will be more effective and less likely to cause bleeding complications than heparin (note col. 1, line 23 through col. 2, line 33; col. 18, line 56 et seq., col. 19, line 33 et seq.).**

**The references of Galin and Iverson clearly show the use of heparin for the inhibition of inflammation of eye and fibrin formation. The reference of Esmon teaches that protein C reduces the amounts of TNF which is responsible for the formation of clots (fibrin) and the inflammation. The reference of Bang shows the superiority of protein C over heparin. The use of protein C which is known to decrease TNF which is the cause of fibrin formation and the inflammation instead of heparin would have been obvious to an artisan since Bang teaches its superiority.**

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4. Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galin or Iverson in combination with Bang and Esmon as applied to claims 22-27 above, and further in view of Stocker.

The primary references do not teach the use of protein S in addition.

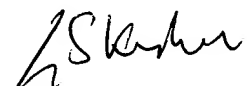
Stocker while disclosing the use of protein C activators teaches that protein S potentiates the action of protein C (note the abstract, column 1, lines 16-19).

The use of protein S in addition, would have been obvious to one of ordinary skill in the art because of the potentiating effect taught by Stocker.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to G. S. Kishore whose telephone number is (703) 308-2440. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-2351.



Gollamudi S. Kishore, PhD  
Primary Examiner  
Group 1500